IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: B. SCHINDLY, et al.	)	Examiner: M. CHORBAJI
Serial No.: 09/314,497	)	Art Unit: 1744
Filed: May 19, 1999	)	Conf. No: 5279
For: **FLOW THROUGH CHEMICAL INDICATOR FOR MEASUREMENT OF ACTIVE BIOCIDAL AGENTS**	)	
Date of Last Office Action: September 8, 2003	)	
Attorney Docket No.: MEDZ 2 01012	)	Cleveland, OH 44114 November 10, 2003

REPLY BRIEF

Mail Stop:
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Brief is responsive to the Examiner's Answer of September 8, 2003.

First, the Appellants disagree with the Examiner's grouping of the claims. Specifically, as asserted in the Appellant's Brief, the claims are grouped into eight groups, and the different reasons for the patentability of each are set forth **Issue 1 - Issue 8**. The Appellants will concur that if claim 1 is patentable, all claims are patentable. However, the claims of the other groups add additional limitations and for the reasons set forth in **Issue 2 - Issue 8** of the Appellant's Brief, the additional limitations set forth in these claims and the presentation of method rather than apparatus claims, raises different issues regarding whether the structure or method is met and regarding the motivation to combine.

Although the Examiner's Answer purports to address **Issue 1 - Issue 8** individually, in many instances, the Examiner does not address the added limitations. Accordingly, it is submitted that these claims are now in condition for allowance.

Response to Arguments

The Examiner's Answer repeatedly asserts, using various phraseology, that the language of column 9, lines 54-62 render it obvious to place the Ignacio sterilization monitor, more commonly known as a chemical indicator or "CI", on the sterilant supplying container of Minerovic.

The Examiner ignores the common knowledge and wisdom in the art as reflected by the Ignacio patent regarding the purpose of chemical indicators and the use to which they are put. Specifically, Ignacio wants an assurance that the medical or other item to be sterilized has, in fact, been sterilized. To this end, Ignacio discloses a paper strip sheathed in a porous jacket, which changes color based on the predetermined parameters of exposure temperature, sterilant concentration, and exposure time. The chemistry is carefully selected such that the prescribed color change only occurs if the conditions to sterilization occurred, e.g., the sterilant is maintained at the prescribed concentration for the time at the prescribed temperature. Thus, the chemical indicator cannot guarantee that a medical item in the sterilizer has been sterilizer, rather it can only indicate that it has been subject to the conditions at which sterilization is known to occur.

In the Minerovic patent, the sterilant supply container **C** is inserted into the well **16**, where projection **40** opens its base, allowing its powdered contents to be released into the well. As water enters the well from the sterilization chamber, it dissolves the powdered reagents, causing a chemical reaction in the well to generate the sterilant. In the well, as the reagents dissolve and react, a very high concentration of sterilant is created. As the liquid in the system is recirculated, this concentration decreases.

The sterilant solution is then circulated through the various channels illustrated in FIGURE 1, bringing the sterilant solution to all portions of the instrument, a coiled endoscope in the embodiment of FIGURE 1. The liquid in the rest of the sterilant chamber is initially water, which flows through it on

its way to the sterilant supply container **C** in the well. The sterilant concentration in the chamber builds in strength with time as the sterilant is distributed. As the concentration of the sterilant in the sterilant chamber increases, the concentration in the well **16** decreases. In most instances, the concentration does not reach equilibrium. The sterilant is a strong oxidant which kills the microbes in an oxidation reaction. Once a molecule of the sterilant undergoes this oxidation reaction, it is used up or spent. Further, the sterilant breaks down with time. This causes an overall decrease in concentration as the cycle progresses. Thus, the time and concentration characteristics of the fluids at the well **16** and in the remainder of the sterilization chamber are not the same.

In the endoscope embodiment illustrated in FIGURE 1, the sterilant fluid flows among various channels. Do all of the channels receive the exact same flow, hence exposure to the same concentrations of sterilant, for the same time, at the same temperature? The current Appellants, being the owners of the Minerovic patent, have spent a significant amount of engineering resources to equalize these flows. However, they would not ask the patient who is about to undergo an endoscopic procedure to bet his/her life on it. Rather, the Appellant suggests the placement of chemical indicators, such as those shown by Ignacio, in the various channels on the various portions of the endoscope to be sterilized. At the end of the sterilization cycle, each of these chemical indicators is examined to be sure that the portions of the endoscope in all regions of the sterilization chamber have been subject to the conditions at which sterilization is known to occur.

However, no one, including Ignacio, suggests placing one of the indicators on the sterilant supply cup **C**. First, it is of no concern whether the sterilant supply cup has been sterilized because it is not going to be used in a medical procedure. Rather, it is going to be removed and thrown in a non-sterile trash receptacle. Second, a chemical indicator placed on the sterilant supply cup is not subject to the same flow, concentration, time, and temperature conditions as the endoscope. Remember, the well saw a high initial concentration

spike which trailed off; whereas, the sterilization chamber saw a concentration which started lower, built to a lower peak, and trailed off. Thus, it is submitted that placing a chemical indicator on the sterilant supply cup of Minerovic is not going to provide the sterility assurance that is reasonably necessary before one can advise the patient undergoing the endoscopic procedure that the endoscope is sterile and safe to use. The Appellant asks the Board members if, when they were undergoing an endoscopic procedure, they would be willing to accept an indicator on the sterilant supply cup as providing sufficient assurance that the endoscope in the sterilization chamber was completely sterilized. Those of ordinary skill in the art would not expect that a chemical indicator of Ignacio placed on the sterilant supply container of Minerovic would perform its intended function of assuring that the medical instrument in the sterilization chamber was sterilized.

Column 9, lines 54-62 of Ignacio allude to another embodiment of the sterilization chamber. Because the Minerovic patent is directed to the sterilant supply container **C**, it merely illustrates an exemplary sterilizer. The Appellant makes another embodiment of the sterilizer, in which the endoscope guiding channels are replaced with a large open well in which items to be individually sterilized are placed. Of course, once an item is removed from the sterilization chamber, microbes in the air can come to rest on it, reinfecting it. Accordingly, as pointed out in Ignacio, such individual items are typically placed in a porous packaging which allows sterilant to enter but blocks airborne microbes from contacting the item. This packaging is typically opened only in the sterile region of the surgical suite or other such location where the item is to be used in its sterile state. When these items are placed in the enlarged well or other chamber, they can have various effects on the flow of the liquid sterilant. For example, one package might block or obstruct the flow to another. As another example, one of the packages might contain an item that was not fully rinsed and contains blood residue, a notorious oxygen scavenger. Liquid sterilant flowing through this package could react rapidly with the blood residue, such that the downstream flow has a reduced

concentration of active sterilant. Enumerable other factors and conditions can exist in the chamber which cause the various items to receive different flows, concentrations, and temperatures of the sterilant. To compensate for these loading and other variations, one typically places a chemical indicator, such as the Ignacio chemical indicator, on each of the packages, in dummy packages, or the like. Sometimes, the operator can tell that some areas of the chamber are more probably going to receive a reduced flow or are otherwise going to be more difficult to sterilize. Since the operator wants to assure sterilization, it is conventional in the art to place the chemical indicator in locations which are deemed most likely not to get sterilized. The sterilant source would surely not be expected to be the region in which it is most difficult to achieve sterility; rather, if anything, one would expect that the high concentrations at the sterilant source would make it the easiest region to sterilize. Determining that the easiest-to-sterilize region has been sterilized, it is submitted, is not an adequate basis for assuming that the most difficult regions to sterilize have been sterilized. Accordingly, it is submitted that Ignacio, at column 9, lines 54-62, which states:

> Sterilization monitors used to monitor vapor phase and liquid phase sterilization processes may be attached as a label to the item to be sterilized, used as masking tape to seal a package containing the item to be sterilized, or simply included in the sterilization chamber along with the item(s) to be sterilized. The sterilization process may involve, for example, sterilization of medical instruments (e.g., fiber optic devices, endoscopic equipment), gloves, linen, parenteral drugs, etc.

This motivates the reader to place chemical indicators in close proximity to the items to be sterilized to check the sterilization conditions at the target sterilization items. It is submitted that it provides no motivation to place chemical indicators on or at the sterilant concentrate source.

So, why to the present Appellants place a chemical indicator on the sterilant source? They do so for reasons not shown or fairly suggested by Ignacio or Minerovic. First, let us look at the situation in which the attendant comes up to the machine of Minerovic and there is a sterilant supply container in the well and no medical devices in the sterilizer chamber. Is the sterilant supply cup full or empty? Remember, that when the sterilant supply container was inserted into the well, its bottom was opened. If the operator picks up the sterilant supply container to see if it is full, and it is, these reagents will flow out the bottom of the sterilant supply container into the well and other areas of the sterilizer. These reagents are powerful reagents with which the operators should avoid contact. Moreover, the sterilizer will often have wetness and drops of water on it. Where the powdered reagent hits this water, even more dangerous chemical compositions can form. All in all, an awkward and time-consuming clean-up operation must follow. On the other hand, if the operator assumes that the sterilant supply container is full, and loads the sterilizer and runs a cycle, valuable time was lost if the sterilant supply container was spent.

As another example, suppose that the sterilant container was subject to improper shipping or storage conditions, such as shipping or storage at elevated temperatures in humid or damp conditions, or the like. Upon opening the sterilizer at the end of the cycle, or even during the cycle by looking through the glass window in the top of the Minerovic sterilizer, one can tell that the sterilant supply container has failed to generate the prescribed amount of sterilant. This enables the operator to abort the current cycle and start over. Even if not caught until the end of the cycle, this saves the operator from fishing through all of the packages, trying to determine whether each of them is sterile when one glance indicates a malfunction at the sterilant source.

Neither these nor numerous other reasons or motivations for placing a chemical indicator on the sterilant source of Minerovic is taught or fairly suggested by Ignacio (or Minerovic).

Looking to **Issue 2** and **claim 8**, which calls for the indicator to be on the top of the container, this provides the added advantage of rapid identification without removing the container from the well. The Examiner merely glances over this limitation, stating that "Ignacio teaches that the location of the indicator can be placed anywhere on the single-use package (col. 9, lines 54-62) including on a porous portion of the top cover or the like". This statement fails to recognize the critical significance of the placement of the indicator on the top where it can be seen when the container is in the well and highlights that Ignacio also fails to recognize it. **Issue 5** (**claim 19**) addresses an analogous placement issue. The Examiner again fails to address or apparently grasp the significance of the placement. **Issue 6** (**claim 20**) addresses another placement issue in which the indicator is placed on the porous material which spans one of the end openings. Again, the Examiner fails to address or dispute the significance of this placement. **Issue 8** (**claim 23**) has a similar issue, but in the context of an overall sterilization system.

Issue 4 (**claim 18**) specifies crystal violet as the indicator. The Examiner has failed to address the Appellant's arguments and citations to the effect that selecting an advantageous item from a long list of alternatives is of patentable significance. **Issue 3** (**claim 15**) addresses an indicator for indicating when a minimum amount of the decontaminant has been generated. Such an indication indicates that sterilization could not have occurred. It does not provide assurance that sterilization did occur at the individual items.

For the reasons set forth above and in the Appellant's Brief, it is submitted that **claims 1-23** (all claims) are now in condition for allowance. An early reversal of the Examiner is requested.

Respectfully submitted,

FAY, SHARPE, FAGAN,
MINNICH & McKEE, LLP

Thomas E. Kocovsky, Jr.
Reg. No. 28,383
1100 Superior Avenue
Seventh Floor
Cleveland, OH 44114-2518
216/861-5582

CERTIFICATE OF MAILING

I hereby certify that this **REPLY BRIEF (x3)** in connection with U.S. Patent Application **Serial No. 09/314,497** is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 10th day of November, 2003.

By: Hilary McNulty